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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,406	07/19/2001	Yoshihiro Sokawa	55600-8004.US00	9683

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EXAMINER
WORTMAN, DONNA C

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/910,406	SOKAWA ET AL.	
	Examiner	Art Unit	
	Donna C. Wortman, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's election without traverse of Invention I, claims 1-11 and 13-15 in Paper No. 14 is acknowledged. Claims 12, 16 and 17 have been canceled. Claims 1-11 and 13-15 as originally filed are pending and under examination.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in reciting "an oral-delivery composition" because it is not clear whether "oral-delivery" intends a particular form or physical property of the claimed composition, or merely an intended use. Claim 1 is also indefinite in reciting "an amount effective to stimulate bloodstream levels of 2',-5'-oligoadenylate synthetase" since it is not clear to what degree synthetase levels would need to be stimulated in order to define clearly the effective amount being claimed, nor is it clear what is intended by "bloodstream levels" since both serum levels and PBMC levels are disclosed, and it is not apparent that the amount of IFN-tau that increases PBMC synthetase levels would be the same as that required to increase serum synthetase levels, e.g.

Claim 2 is indefinite because it depends from claim 1 and recites "further comprises an oral delivery vehicle containing IFN-tau." It is not clear whether claim 2 intends to recite the presence of additional IFN-tau, in addition to the IFN-tau recited in claim 1. If not, it is suggested that the word "further" be deleted.

Claims 4-10 are indefinite in reciting "the dosage ... is ... Units/day" since "Units/day" would seem to describe a rate of administration of a composition rather than an actual amount present in a composition.

Claim 11 is indefinite in reciting "wherein the dosage ... avoids the *tunica mucosa oris*" because it is not clear what, if any, property of the "dosage" is intended, e.g., is the cited terminology intended to convey a property of the dosage form, or the route of administration of the composition?

Claim 13 is also indefinite in reciting "wherein said composition avoids the absorption ... through the *tunica mucosa oris*" because it is not clear what property of the composition is intended, e.g., is the cited terminology intended to convey some property of the composition, or the route of administration?

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 and 13-15 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent 6,372,206 to Soos et al. Soos et al. disclose the use of a therapeutically effective amount of orally administered ovine interferon-tau for treatment of viral disease, including hepatitis C (see, e.g., col. 4, lines 25-60). Soos et al. also disclose advantages of oral administration of interferon-tau, including lower level of anti-interferon antibodies in orally treated subjects as compared to those treated with injected interferon-tau (col. 9, lines 5-24, e.g.). Soos et al. disclose formulations of interferon-tau that are suitable for oral administration, including tablets, capsules, slow release preparations, and liquids, e.g. (col. 15, lines 3-40), as well as therapeutically effective dosages that vary as necessary (e.g., col. 4, lines 33-36; col. 15, lines 41-53). The orally administered interferon-tau compositions of Soos et al. are deemed to be the same as, or only slightly different from those instantly claimed, because the instant claims do not distinguish over the prior art interferon-tau pharmaceutical composition since no particular dosage form

or formulation is recited; because, interpreting the claims in light of the specification, it is noted that the trials described on pages 16-20 use an orally administered pharmaceutical composition that comprises "a solution" at a concentration of 1 mg/ml that is administered orally with a syringe; and because the claims are indefinite as described above at least to the extent that "Units/day" appears to describe a rate of administration of interferon-tau rather than the amount present in a given composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
February 20, 2003